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EXAMINER	
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ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,267	SCHNECK ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-142 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-142 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4-41 and 46-65, drawn to a solid support comprising an MHC class I molecule, an MHC class II molecule or a CD1 molecule and at least one lymphocyte affecting molecule that is a T cell co-stimulatory molecule, an adhesion molecule, a T cell growth factor or regulatory T cell inducer molecule that is a cytokine or a superantigen, an apoptosis-inducing molecule, or an antibody that specifically binds to CD28, HVEM, CD40L, OX40 or 4-1BB, classified in Class 424, subclass 193.1.

II. Claims 42-45 and 67-70, drawn to a solid support comprising a TCR that engages a B cell surface MHC/antigen complex, and at least one B cell affecting molecule that is a CD40 ligand, a B cell growth factor, an inducer of apoptosis, or a cytokine, classified in Class 424, subclass 185.1.

III. Claims 42-45, drawn to a solid support comprising an antibody that engages a B cell surface MHC/antigen complex, and at least one B cell affecting molecule that is a CD40 ligand, a B cell growth factor, an inducer of apoptosis, or a cytokine, classified in Class 424, subclass 178.1.

IV. Claims 42-45, drawn to a solid support comprising an antibody that engages B cell surface immunoglobulins, and at least one B cell affecting molecule that is a CD40 ligand, a B cell growth factor, an inducer of apoptosis, or a cytokine, classified in Class 424, subclass 180.1.

V. Claims 71-81, drawn to a method of inducing the formation of antigen-specific T cells, said method comprising contacting and isolated preparation comprising a plurality of precursor T cells with at least one first solid support, classified in Class 435, subclass 7.2.

VI. Claims 71 and 82-87, drawn to a method of increasing the number or percentage of antigen-specific T cells and administering them to a patient, classified in Class 435, subclass 7.2 and Class 424, subclass 185.1, respectively.

VII. Claims 88-90, drawn to a method of suppressing an immune response in a patient, said method comprising administering a preparation comprising a plurality of particles comprising at least one T cell affecting molecule that is an apoptosis-inducing molecule, at least one antigen presenting complex that is an MHC class I complex, an MHC class II complex or a CD1 complex and a pharmaceutically acceptable carrier, classified in Class 424, subclass 193.1.

VIII. Claims 88 and 89, drawn to a method of up regulating an immune response in a patient, said method comprising administering a preparation comprising a plurality of particles comprising at least one T cell affecting molecule that is an apoptosis-inducing molecule, a regulatory T cell inducing molecule, a T cell costimulatory molecule, an adhesion molecule or a T cell growth factor, at least one antigen presenting complex that is an MHC class I molecule, an MHC class II molecule or a CD1 molecule, and a pharmaceutically acceptable carrier, classified in Class 424, subclass 193.1.

IX. Claims 91-114 drawn to a cell comprising at least one lymphocyte affecting molecule that is a T cell-affecting molecule that is an apoptosis-inducing molecule, a regulatory T cell inducing molecule, a T cell costimulatory molecule, an adhesion molecule or a T cell growth factor, and at least one molecular complex that is an antigen presenting complex that is MHC class I or MHC class II, classified in Class 435, subclass 325.

X. Claims 115-117, drawn to a cell comprising at least one B cell affecting molecule and a molecular complex that is a TCR fusion protein, classified in Class 435, subclass 325.

XI. Claims 118-125, drawn to a method of inducing the formation of antigen specific T cells or of increasing the number or percentage of antigen-specific T cells, said method comprising the step of contacting an isolated preparation comprising a plurality of precursor T cells with a plurality of cells of claim 92, classified in Class 435, subclass 377.

XII. Claims 118 and 126-133, drawn to a method of inducing the formation of antigen specific T cells and up-regulating an immune response in a patient, said method comprising administering a plurality of the cells of claim 92, classified in Class 424, subclass 93.7.

XIII. Claims 118 and 126-133, drawn to a method of inducing the formation of antigen specific T cells and a method of suppressing an immune response in a patient, said method comprising administering a plurality of the cells of claim 92 and a pharmaceutically acceptable carrier to a patient, classified in Class 424, subclass 93.71.

XIV. Claims 134-139, drawn to a method of increasing the number or percentage of antibody-producing B cells in a population, said method comprising contacting an isolated preparation comprising a plurality of precursor B cells with at least one first solid support of claim 42, wherein the solid support comprises an antibody that recognizes immunoglobulins on the surface of B cells, classified in Class 435, subclass 7.24.

XV. Claims 134-139, drawn to a method of increasing the number or percentage of antibody-producing B cells in a population, said method comprising contacted an isolated preparation comprising a plurality of precursor B cells with at least one first solid support of claim 42, wherein the solid support comprises an antibody that recognizes a specific MHC/peptide complex on the surface of B cells, classified in Class 424, subclass 7.1.

XVI. Claims 134-139, drawn to a method of increasing the number or percentage of antibody-producing B cells in a population, said method comprising contacted an isolated preparation comprising a plurality of precursor B cells with at least one first solid support of claim 42 comprising a TCR that engages a B cell surface MHC/antigen complex, classified in Class 435, subclass 7.1.

XVII. Claims 140-142, drawn to a method of up-regulating an immune response in a patient, said method comprising administering a plurality of particles and a pharmaceutically acceptable carrier, wherein the said plurality of particles comprises at least one B cell affecting molecule and at least one TCR that engages an MHC/antigen complex on a B cell surface, classified in Class 424, subclass 185.1.

XVIII. Claims 140-142, drawn to a method of suppressing an immune response in a patient, said method comprising administering a plurality of particles and a pharmaceutically acceptable carrier, wherein the said plurality of particles comprises at least one B cell affecting molecule and at least one TCR that engages an MHC/antigen complex on a B cell surface, classified in Class 424, subclass 185.1.

XIX. Claims 140-142, drawn to a method of up-regulating an immune response in a patient, said method comprising administering a plurality of particles and a pharmaceutically acceptable carrier, wherein the said plurality of particles comprises at least one B cell affecting molecule and at least one antibody that engages an MHC/antigen complex on a B cell surface, classified in Class 424, subclass 180.1.

XX. Claims 140-142, drawn to a method of suppressing an immune response in a patient, said method comprising administering a plurality of particles and a pharmaceutically acceptable carrier, wherein the said plurality of particles comprises at least one B cell affecting molecule and at least one antibody that engages an MHC/antigen complex on a B cell surface, classified in Class 424, subclass 182.1.

XXI. Claims 140-142, drawn to a method of up-regulating an immune response in a patient, said method comprising administering a plurality of particles and a pharmaceutically acceptable carrier, wherein the said plurality of particles comprises at least one B cell affecting molecule and at least one antibody that engages B cell surface immunoglobulins, classified in Class 424, subclass 178.1.

XXII. Claims 140-142, drawn to a method of suppressing an immune response in a patient, said method comprising administering a plurality of particles and a pharmaceutically acceptable carrier, wherein the said plurality of particles comprises at least one B cell affecting molecule and at least one antibody that engages B cell surface immunoglobulins, classified in Class 424, subclass 179.1.

2. Claims 1-3 link Inventions I, II, II and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1-3. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does

not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

5. Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

6. Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

7. Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

8. Inventions IX and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

9. Inventions IX and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

10. Inventions IX and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

11. Inventions II and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

12. Inventions II and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

13. Inventions II and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

14. Inventions II and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

15. Inventions II and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

16. Inventions II and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.
In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

17. Inventions II and XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

18. Inventions II and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

19. Inventions II and XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

20. (Invention I) and (Inventions II-IV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different Inventions I and II-IV comprise solid supports that inhibit or suppress a differently restricted immune response, *i.e,* T cell mediated (I) versus humoral (II-IV).

21. Inventions II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a solid support may comprise an antibody that engages B cell surface immunoglobulins or an antibody that engages a B cell surface MHC/antigen complex for the purpose of regulating an immune response. The subcombination has separate utility such as for increasing the number of antigen-specific B cells.

22. Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the cell of Invention IX comprises an MHC class I or class II molecule, whereas the cell of Invention X comprises a molecular complex that is a TCR fusion protein. Class I molecules are different proteins than TCR fusion proteins and engage different ligands.

23. Inventions (IX and X) and Inventions (I-IV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the cell of Invention IX comprises an MHC class I or class II molecule, whereas the cell of Invention X comprises a molecular complex that is a TCR fusion protein and the solid support of Invention I comprises an MHC or CD1 molecule and the solid support of Invention II comprises a TCR specific for MHC/peptide, whereas the

solid support of Invention III comprises an antibody that engages an MHC/peptide complex, whereas the solid support of Invention IV comprises an antibody that engages B cell surface immunoglobulins. MHC molecules are different proteins than TCR proteins and they engage different ligands, and cells are different from solid supports in that they present many additional endogenous molecules on their surface.

24. Inventions V-VIII and XI-XXII are different methods.

These inventions require different ingredients and process steps to accomplish the use of: inducing the formation of antigen-specific T cells *in vitro* by contacting precursor T cells with a solid support comprising an MHC class I, MHC class II or CD1 molecule (V) and administering them to a patient (VI), suppressing an immune response *in vivo* comprising administering particles comprising an apoptosis-inducing molecule and one of an MHC class I, MHC class II or CD1 molecule (VII), upregulating an immune response *in vivo* comprising administering particles comprising an MHC class I, MHC class II or CD1 molecule and a T cell affecting molecule (VIII), inducing the formation of antigen specific T cells by contacting said T cells with cells comprising an MHC class I or MHC class II molecule and a T cell affecting molecule *in vitro* (XI), inducing the formation of antigen specific T cells by administering the cells comprising an MHC class I or MHC class II molecule to a patient (XII), inducing the formation of antigen specific T cells and suppressing an immune response in a patient by administering the cells comprising an MHC class I or MHC class II molecule (XIII), increasing the number or percentage of antibody producing B cells in a population by contacting precursor B cells with a solid support that comprises an antibody that recognizes B cell surface immunoglobulins (XIV) or an antibody that recognizes a specific MHC/peptide complex on the B cell surface (XV), or a TCR that binds a particular MHC/peptide complex (XVI), a method of up-regulating an immune response in a patient comprising administering particles that comprise a TCR that engages an MHC/antigen complex on a B cell (XVII) or an antibody that engages an MHC/antigen complex on a B cell (XIX) or an antibody that engages B cell surface immunoglobulins (XXI), or a method of suppressing an immune response in a patient comprising administering particles that comprise a TCR that engages an MHC/antigen complex on a B cell (XVIII) or an antibody that engages an MHC/antigen complex on a B cell (XX) or an antibody that engages B cell surface immunoglobulins (XXII).
Therefore they are patentably distinct.

25. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-XXII is not required for any other group from Groups I-XXII and Groups I-XXII have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

26. **If Applicant elects the Invention of Group I**, Applicant is further required to (1) elect a single disclosed species (***a specific solid support comprising a specific T lymphocyte affecting molecule and a specific antigen presenting molecule***, for example, a bead comprising MHC class I with a single peptide antigen bound in the binding cleft and a T cell co-stimulatory molecule that is B7-1 bound to a bead) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

27. **If Applicant elects the Invention of Group II**, Applicant is further required to (1) elect a single disclosed species (***a specific solid support comprising a specific B lymphocyte affecting molecule and a TCR specific for a specific MHC/peptide complex***, for example, CD40 ligand and a TCR complex comprising an alpha chain and a beta chain as two separate chains bound to a bead) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

28. **If Applicant elects the Invention of Group III**, Applicant is further required to (1) elect a single disclosed species (***a specific solid support comprising a specific B lymphocyte affecting molecule and a specific antibody that recognizes an MHC/peptide complex***, for example, CD40 ligand and an antibody specific for MHC class I/peptide bound to a bead) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.
These species are distinct because their structures are different.

29. **If Applicant elects the Invention of Group IV**, Applicant is further required to (1) elect a single disclosed species (***a specific solid support comprising a specific B lymphocyte affecting molecule***, for example, CD40 ligand and an antibody specific for B cell surface immunoglobulins bound to a bead) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

30. **If Applicant elects the Invention of Group V**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (***a specific solid support comprising a specific T lymphocyte affecting molecule and a specific antigen presenting complex and a specific antigen-specific T cell and specific method steps,*** for example, B7-1 and MHC class I containing identical peptide antigens, wherein the B7-1 and MHC class I complex are bound to a bead and CTL and incubating the first cell population with only a first solid support and wherein the first cell population is a heterogeneous cell population) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

31. **If Applicant elects the Invention of Group VI**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (***a specific solid support comprising a specific T lymphocyte affecting molecule and a specific antigen presenting complex and a specific antigen-specific T cell and specific method steps, and wherein the patient has a specific disease or condition and wherein the precursor T cells are obtained from a specific source,*** for example, B7-1 and MHC class I containing identical peptide antigens, wherein the B7-1 and MHC class I complex are bound to a bead and CTL and incubating the first cell population with only a first solid support and wherein the first cell population is a heterogeneous cell population and wherein the precursor T cells are obtained from the patient) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

32. **If Applicant elects the Invention of Group VII**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (***a specific solid support comprising a specific apoptosis-inducing molecule and a specific antigen presenting complex,*** for example, TNFα and MHC class I containing identical peptide antigens, wherein the TNFα and MHC class I complex are bound to a bead) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

33. **If Applicant elects the Invention of Group VIII**, Applicant is further required to (1) elect a single disclosed species (***a cell comprising a specific T lymphocyte affecting molecule and a specific antigen presenting complex,*** for example, B7-1 and MHC class I containing identical peptide antigens, wherein the B7-1 and MHC class I complex are bound to a bead) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

34. **If Applicant elects the Invention of Group IX**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (***a cell comprising a specific T lymphocyte affecting molecule and a specific antigen presenting complex,*** for example, B7-1 and MHC class I containing identical peptide antigens, wherein the MHC class I molecule is a fusion protein comprising an MHC class I a chain and a first Ig heavy chain and a second MHC class I a chain and a second Ig heavy chain and wherein the two peptide binding clefts bind the same antigenic peptide) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

35. **If Applicant elects the Invention of Group X**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (***a cell comprising a specific B lymphocyte affecting molecule and a TCR fusion protein,*** for example, CD40 ligand and the ab TCR fusion protein recited in instant claim 115) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

36. **If Applicant elects the Invention of Group XI**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (***a cell comprising a specific T lymphocyte affecting molecule and a specific antigen presenting complex and specific antigen-specific T cells and specific method steps,*** for example, B7-1 and MHC class I containing identical peptide antigens, wherein the MHC class I molecule is a fusion protein comprising an MHC class I a chain and a first Ig heavy chain and a second MHC class I a chain and a second Ig heavy chain and wherein the two peptide binding clefts bind the same antigenic peptide and antigen specific T cells that are CTL and contacting the isolated preparation that is a homogenous population and the preparation is only contacted with a first cell population) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

37. **If Applicant elects the Invention of Group XII**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (***a cell comprising a specific T lymphocyte affecting molecule and a specific antigen presenting complex and specific antigen-specific T cells and specific method steps and wherein the patient has a specific disease or condition and a specific source of precursor T cells,*** for example, B7-1 and MHC class I containing identical peptide antigens, wherein the MHC class I molecule is a fusion protein comprising an MHC class I a chain and a first Ig heavy chain and a second MHC class I a chain and a second Ig heavy chain and wherein the two peptide binding clefts bind the same antigenic peptide and antigen specific T cells that are CTL and contacting the isolated preparation that is a homogenous population and the preparation is only contacted with a first cell population, wherein the patient has cancer, and wherein the precursor T cells are obtained from the patient) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

38. **If Applicant elects the Invention of Group XIII**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (***a cell comprising a specific T lymphocyte affecting molecule and a specific antigen presenting complex and specific antigen-specific T cells and specific method steps and a specific source of precursor T cells,*** for example, TNFα and MHC class I containing identical peptide antigens, wherein the MHC class I molecule is a fusion protein comprising an MHC class I a chain and a first Ig heavy chain and a second MHC class I a chain and a second Ig heavy chain and wherein the two peptide binding clefts bind the same antigenic peptide and antigen specific T cells that are CTL and contacting the isolated preparation that is a homogenous population and the preparation is only contacted with a first cell population, and wherein the precursor T cells are obtained from the patient) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

39. **If Applicant elects the Invention of Group XIV**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (***a specific solid support comprising a specific B lymphocyte affecting molecule***, for example, CD40 ligand and an antibody that binds B cell surface immunoglobulins both bound to a bead) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

40. **If Applicant elects the Invention of Group XV**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (***a specific solid support comprising a specific B lymphocyte affecting molecule***, for example, CD40 ligand and an antibody that recognizes a specific MHC/peptide complex on the surface of B cells, both bound to a bead) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

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41. **If Applicant elects the Invention of Group XVI**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (***a specific solid support comprising a specific B lymphocyte affecting molecule and a TCR specific for a specific MHC/peptide complex***, for example, CD40 ligand and a TCR complex comprising an alpha chain and a beta chain as two separate chains, both bound to a bead) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

42. **If Applicant elects the Invention of Group XVII or of Group XVIII**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (***a specific solid support comprising a specific B lymphocyte affecting molecule and a TCR specific for a specific MHC/peptide complex***, for example, CD40 ligand and a TCR complex comprising an alpha chain and a beta chain as two separate chains, both bound to a bead) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

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43. **If Applicant elects the Invention of Group XIX or of Group XX**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (***a specific solid support comprising a specific B lymphocyte affecting molecule and an antibody that engages a specific MHC/peptide complex***, for example, CD40 ligand and an antibody that engages one specific MHC/peptide complex bound to a bead) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

44. **If Applicant elects the Invention of Group XXI or of Group XXII**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (***a specific solid support comprising a specific B lymphocyte affecting molecule and an antibody that engages B cell surface immunoglobulins***, for example, CD40 ligand and an antibody that engages one specific MHC/peptide complex bound to a bead) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

45. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

46. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

47. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

48. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

49. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

50. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

51. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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